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REMARKS

The pending claims were rejected under 35 USC 103(a) over various combinations of references and claim 15 was objected to as being allowable, but depending from a rejected base claim. Applicant respectfully traverses these rejections.

1. Grounds of Rejection Unclear

Certain claims were rejected in paragraph 4 of the Final Office Action under 35 USC 103(a) over Gates et al. (5,522,875) in view of Termin et al. (5,378,2389). However, the body of the rejection fails to mention Gates in any manner, but instead makes references to a "Bens" reference. The stated grounds of rejection (i.e., Gates) do not appear to be a typographical error since the correct patent number for Gates is also provided. The references made in the body of the rejection appear to relate more to Bens than Gates. Subsequent statements of rejection include Bens, and not Gates. As such, Applicant will respond under the assumption that Bens was the intended reference.

Clarification of the formal record is requested. Furthermore, if Gates should have been cited, the finality of this action must be withdrawn and a new Office Action presented.

2. No Prima Facie Case of Obviousness

As the Examiner is well aware, a proper prima facie case of obviousness must establish some motivation that exists (other than hindsight and a reading of the pending claims) that would lead one of ordinary skill in the art to combine the references as suggested.

In the present case, the Examiner has asserted that such a motivation would be that the larger helix of Termin, if used with Bens would "displace from the immediate electrode the trauma caused to the heart wall by the helix." The simple fact is that the vast majority of helical or screw-type active fixation tips also serve as electrodes without error or complication. Thus, the "trauma"

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asserted by the Examiner is not actually a concern to those who practice in the art. As such, this would not be motivation to make a combination; particularly one that would render the device inoperative for its intended purpose.

Furthermore, Bens actually teaches using the helix as an electrode making such a motivation statement entirely moot. Col 5, lines 43-49. Regardless of how large of a diameter the helix formed, the "trauma" site would be coincident with the electrode surface.

In formulating a *prima facie* case of obviousness, the claims must be considered as whole and the references must also be considered in their entireties. The Bens device includes an active fixation tip or helix that upon rotation must pierce and advance through the cardiac muscle. Bens is explicit that the tip must be able to rotate and cause fixation in this manner. Col. 2 lines, 37-43, line 63- Col. 3, line 2. Providing a larger diameter than the lead body, upon expansion reduces the axial driving force that may be imparted through rotation within an already elongated, narrow diameter catheter. Thus, providing a structure like that of Termin with outwardly expanding spring force (relevant for stents, not for endocardial leads such as Bens) would provide literally no benefit, would reduce the ability to fixate the lead, and thus, would obviate the intended purpose of the Bens device.

The relevant portions of Termin provide for a helical structure that engage an interior wall of a vein or artery; thus, significantly larger in diameter than the fixation helix of the endocardial lead of Bens. This structure includes a relatively straight wire that when heated or released expands a great deal to brace against the vessel wall. The Bens device is guided to a very specific location within the heart and the helix is advanced through cardiac muscle to secure the lead. A helix having a larger diameter than the lead body would serve no benefit and lead to the inoperability of Bens.

Thus, the only possible motivation for making such a combination is the picking and choosing of elements from disparate, non-combinable references for the sole purpose of forging a rejection based entirely on a hindsight reading of

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the present claims. When considered as a whole, the present claims are quite distinct from the cited references, alone or in combination.

Applicant respectfully asserts that the present claims are in condition for allowance and notice of the same is respectfully requested. Should any issues remain, the Examiner is requested to telephone the undersigned attorney to expedite prosecution.

Respectfully submitted,

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